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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LEWIS, AARON J	

ART UNIT	PAPER NUMBER
3743	

DATE MAILED: 11/04/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/837,800	JAPUNTICH ET AL.	
	Examiner	Art Unit	
	AARON J. LEWIS	3743	

-- The MAILING DATE of this communication appears on the cover sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08/06/2003 (AMENDMENT)* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-37,50-53 and 55-85* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-37,50-53 and 55-85* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 33-37,76-78,50-53,55-63,65-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al. ('516) in view of McKim ('168).

As to claim 33, Simpson et al. disclose a filtering face mask that comprises: a mask body (1,2) that is adapted to fit over the nose and mouth of a wearer, the mask body comprising a filtration layer (page 1, lines 108-113) through which inhaled air may pass before being inhaled by a wearer of the face mask; and an exhalation valve (fig.2) that is attached to the mask body, the exhalation valve allowing air exhaled by a wearer to pass from an interior of the mask body to its exterior without having to pass through the filtration layer, the exhalation valve comprising: a valve seat that comprises: a seal surface (page 2, lines 37-50 and #19); and an orifice (16) that is circumscribed by the seal surface; and a single flexible flap (15) that has only one stationary portion (page 2, lines 46-50) and only one free portion and a circumferential edge, the circumferential edge having a first segment that is associated with the one stationary portion of the flap so as to remain at rest during an exhalation and having a second segment that is associated with the one free portion of the flexible flap so as to be lifted away from the seal surface during an exhalation, the second segment of the circumferential edge also

being located below the first segment when the filtering face mask is worn on a person (fig.1).

The differences between Simpson et al. and claim 33 are the flexible flap being mounted to the valve seat such that the one free portion of the flap exhibits a curvature when viewed from the side in the closed position and is pressed towards the seal surface in an abutting relationship with it, under any orientation of the exhalation valve, when a fluid is not passing through the orifice and an orifice having a cross-sectional area greater than about 2 centimeters.

While Simpson et al. do not expressly disclose the size of orifice (16), it is submitted that the size of the orifice can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular orifice size. One of ordinary skill would have realized that factors which require an adjustment in orifice size in Simpson et al. include the accommodation of exhaled volumes from patients of having different exhaled volumes due to differences in age and physical condition. That is, one of ordinary skill would have realized a need to adjust the sizes of orifices (16) in Simpson et al. to accommodate differences in exhaled volumes from patients of different ages and differing physical condition.

McKim teaches a flexible flap being mounted to the valve seat such that the one free portion (opposite the fixed portion #14a as illustrated in figs.1 and 3) of the flap exhibits a curvature when viewed from the side and is pressed towards the seal surface in an abutting relationship with it when a fluid is not passing through the orifice for the purpose of seating quickly, effectively and without float or bounce after each opening (col.1, lines 64-72).

It would have been obvious to modify the exhalation valve of Simpson et al. to be mounted to the valve seat such that the one free portion (opposite the fixed portion

#14a as illustrated in figs.1 and 3) of the flap exhibits a curvature when viewed from the side and is pressed towards the seal surface in an abutting relationship with it when a fluid is not passing through the orifice for because it would have provided for seating quickly, effectively and without float or bounce after each opening as taught by McKim.

As to claim 34, the flexible flap of Simpson et al. as modified by McKim is not wholly circular when view from the front (see fig.2 of McKim).

As to claim 35, Simpson et al. (figs.1 and 2) illustrate the second segment of the circumferential edge of the flexible flap having a circular curvature that corresponds to a circularly shaped seal surface disposed beneath the second segment of the flap's circumferential edge.

As to claims 36 and 37, the valve seat of Simpson et al. as modified by McKim (#15 and #28 of fig.3) illustrates a planar flap retaining surface, the flexible flap being mounted to the flap-retaining surface.

As to claim 76, the flap retaining surface includes two securement points both disposed outside a region encompassed by the orifice (e.g. see #17 of McKim).

As to claims 77 and 78, the curvature in the flexible flap (14) of McKim (fig.1) extends from a point where the flap os mounted to the valve seat to a second point where the free portion of the flexible flap makes contact with the seal surface and the curvature does not have an inflection point.

As to claim 50, Simpson et al. (fig.2) discloses the valve seat including a flange portion that defines a mounting surface for the valve seat, which surface extends 360 degrees around the valve seat an its base and enables the valve seat to be secured to the mask body.

As to claims 51-53, McKim (fig.1) teaches the flexible flap assuming a curved profile, when in its closed state, the extends in from where the flexible flap contacts a retaining

surface on the valve seat to where the second portion of the flexible flap contacts the seal surface of the valve body portion. Further, the flap retaining surface is oriented transversely to and adjacent the orifice in Simpson et al. and in McKim (fig.2).

As to claim 55, the flexible flap of Simpson et al. is mounted to the valve seat in cantilever fashion.

As to claim 56, the particular material from which the valve seat of Simpson et al. is made and the manner of making the valve seat can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular material including a relatively light weight plastic. Inasmuch as Simpson et al. (page 2, lines 37-65) disclose the valve flap being made from plastic and/or rubber material, it would have been obvious to make the valve seat from any well known material which would achieve known or expected results including a plastic and/or rubber material because the use of a valve seat of the same material as the valve flap would have provided for more effective physically cooperation.

As to claim 57, Simpson et al. disclose the flexible flap being pressed towards the seal surface such that there is a substantially uniform seal when the valve is in a closed position (page 2, lines 39-42). The seal (figs.2 and 3) of Simpson et al. are illustrated as being substantially uniform and since the flexible flap (15) of Simpson et al. is disclosed of being made from plastic and since known physical characteristices of plastics include flexibility and resiliency, the flap (15) of Simpson et al. being made from plastic is fully capable of providing the recited function of "...capable of allowing the flap to display a bias towards the seal surface.".

As to claim 58, the bias of the valve flap of Simpson et al. as modified by McKim is generated by the mounting of the flap to the valve seat as illustrated by McKim.

As to claims 59 and 60, the degree of a seal between the valve flap and valve seat sealing surface of Simpson et al. can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular degree of seal. Further, it stands to reason that one oridinary skill in the art would strive to make a face mask in accordance with at least minimum current government standards of operation including one having a valve flap having a stress relaxation sufficient to keep the flexible flap in an abutting relationship to the seal surface under any static orientation for 24 hrs. at 70 degrees centigrade. The flexible flaps (15,18) of Simpson et al. is disclosed as being made of plastic and/or rubber for example (page 2, lines 39 and line 53). It would have been obvious to make the flexible flap from any well known flexible material including an elastomeric rubber such a polyisoprene as mere substitution of one well known flexible material for another and because elastomeric rubber is a well known material from which to make valve flaps.

As to claim 61, the particular dimensions, the particular material including the hardness of the material of the flexible flap (15,14) of Simpson et al. can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular dimensions nor in any particular constituency.

As to claim 62, Fig.2 of Simpson et al. illustrate the flexible flap (15) to be longer in the direction extending from the first segment of the circumferential edge to the second segment.

As to claim 63, while Simpson et al. is silent as to the relative surface areas of the fixed and free portions of flap (15), it is submitted that the particular relative amounts of the fixed and free portions can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular relative amounts including 10-25% fixed and 75-90% free.

As to claim 65, Simpson et al. (page 1, lines 116-123) disclose the mask body is cup-shaped and comprises at least one shaping layer for providing structure to the mask, and a filtration layer, the at least one shaping layer being located outside of the filtration layer on the mask body.

As to claims 66 and 67, while Simpson et al. do not address the particular volume of a wearer's exhalation exiting the exhalation valve (12), it is submitted that since the exhalation valve (12) is expressly disclosed as opening in response to a wearer's exhalation, the valve of Simpson et al. is fully capable of providing the recited function inasmuch as it would remain opened as long as a wearer is exhaling which would enable most if not all of the volume including 60-73% of gas exhaled by a wearer to pass through valve 12 of Simpson et al..

As to claim 68, the exhalation valve of Simpson et al. (fig.1) is positioned on the mask body substantially opposite to a wearer's mouth.

As to claim 69, the flap retaining surfaces of Simpson et al. and McKim are located around the periphery of the orifice; therefore, the flap retaining surfaces are not disposed substantially in the path of the exhale flow stream.

As to claim 70, Simpson et al. (fig.2) disclose a plurality of openings (16) seperated by cross members, the openings being disposed within the orifice and beneath a point where the flexible flap (12) is mounted to the valve seat when viewing the filtering face mask from the front in an upright position (fig.1).

As to claim 71, Simpson et al. as discussed above with respect to claim 70 discloses exhaled passing primarily through a plrality of openings (16).

As to claim 72, the valve seat of Simpson et al. (fig.2) includes a flap retaining surface (page 2, lines 46-50) that is located outside the region defined by the plurality of openings (16).

3. Claims 73-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al. in view of McKim as applied to claims 33-37,76-78,50-53,55-63,65-72 above, and further in view of Shindel ('277).

The difference between Simpson et al. as modified by McKim and claim 73 is a valve cover, the valve cover having an opening that allows exhaled air to pass therethrough and also having a surface that holds the flexible flap against the flap-retaining surface on the valve seat.

Shindel (col.2, lines 59-66) teaches a valve cover (7), the valve cover having an opening that allows exhaled air to pass therethrough and also having a surface (14) that holds the flexible flap against the flap-retaining surface on the valve seat. Shindel cites the advantages of simplicity of arrangement and ready removability of the cover when desired which would allow for replacement and/or cleaning of the valve and orifices. Additionally, the cover would have provided a means for directing fluid which passes through the orifice as well as protecting the valve flap against debris.

It would have been obvious further modify the valve of Simpson et al. to add a valve cover because it would have provided for simplicity of arrangement and ready removability of the cover when desired which would allow for replacement and/or cleaning of the valve and orifices and because it would have provided a means for directing exhaled gas away from a wearer's face and provided a means for protecting the valve flap against debris as taught by Shindel.

As to claims 74 and 75, the flexible flap of Simpson et al. as further modified by Shindel is mounted the valve seat by mechanical clamping (fig.2 of Shindel) and the flap-retaining surface (5) of Shindel is disposed on one side of the seal surface (fig.2 of Shindel).

4. Claims 79,80-82 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al. in view of McKim as applied to claims 33-37,76-78,50-53,55-63,65-72 above, and further in view of Warbasse ('706).

The difference between Simpson et al. as modified by McKim and claim 79 is a valve cover that has an opening that permits exhaled air to pass therethrough, the valve cover also having a fluid impermeable ceiling that increases in height in the direction of the flexible flap from the first segment of the circumferential edge towards the second segment of the edge.

Warbasse (fig.2) teaches a valve cover (11) that has an opening that permits exhaled air to pass therethrough, the valve cover also having a fluid impermeable ceiling that increases in height in the direction of the flexible flap from the first segment of the circumferential edge towards the second segment of the edge.

It would have been obvious to further modify the mask of Simpson et al. to provide a valve cover because it would have provided a means for protecting the valve flap, controlling the movement of the valve flap, and controlling the direction of fluid flow exiting the mask via the valve as taught by Warbasse.

As to claim 64, the flexible flap and valve cover of Simpson et al. as further modified by Warbasse are positioned on the valve seat such that exhaled air is deflected downward during an exhalation when the filtering face mask is worn on a person (fig.2 of Warbasse).

As to claim 80, the opening in the valve cover of Simpson et al. as further modified by Warbasse (fig.2) is positioned directly in the path of fluid flow approximately parallel to the path traced the by second segment of the circumferential edge during opening and closing of the free portion of the flexible flap (12).

As to claims 81 and 82, the valve seat's orifice (16) of Simpson et al. (fig.2) is circular and has one or more cross members disposed within the orifice.

5. Claims 83-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al. in view of McKim as applied to claims 33-37,76-78,50-53,55-63,65-72 above, and further in view of Braun ('362).

The difference between Simpson et al. as modified by McKim and claim 83 are cross members which are slightly recessed beneath the seal surface when viewed from a side elevation.

Braun teaches cross members (19,20) disposed within the orifice and which are slightly recessed beneath the seal surface (18) for the purpose of increasing the sealing force (col.4, lines 36-41). The cross members would assist in preventing the flexible flap from being drawn into the orifice during an inhalation.

It would have been obvious to further modify the position of the cross members of Simpson et al. to slightly recess them beneath the seal surface because it would have increased the sealing force of the valve as taught by Braun.

As to claim 84, the shape of the orifice (16) of Simpson et al. does not wholly correspond to the shape of the seal surface.

As to claim 85, Braun teaches a seal ridge (18) which extends upwardly of a peripheral mounting flange for the purpose of increasing the sealing force.

Response to Arguments

Applicants' arguments that the flap (15) of Simson et al. can only be pressed towards the seal surface under the force of gravity when the mask is in an upright position is disagreed with because there is no support in the disclosure of Simpson et al. which for a basis for such a position. The mask body of Simpson et al. (fig.1) is illustrated and disclosed as filtering inhaled air and releasing exhaled air through exhalation valve (fig.2). The mask of Simpson et al. is disclosed as being worn by persons in which the ambient atmosphere contains gaseous or vaporous contaminants (page 1, lines 24-28). In order for the mask of Simpson et al. to function as it is intended (and there is no reasons to even suspect that is does not), the exhalation valve (fig.2) must remain closed until a wearer exhales; otherwise, gaseous or vaporous contaminants would leak into the interior of the mask body and be inhaled by such a wearer.

Applicants' arguments that neither Simpson et al. nor McKim suggest the benefits of the present invention are disagreed with because the combination thereof teaches the claimed structure and therefore is fully capable of providing the recited function(s).

The Bowers and Fabin Affidavits have been considered but are not persuasive for the following reasons: Applicants' argument that McKim constitutes nonanalogous art because it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, is is submitted that one of ordinary skill would look to the art of valves (which includes McKim ('618)) to address problems associated with the effectiveness of valve seating of a valve element which is used for controlling the direction of flow of breathable air through such a valve. McKim clearly addresses the problem of effectiveness of valve seating by non-aligning the flap retaining surface and the seal surface relative to each other thereby providing effective seating without float or bounce after each opening (col.1, lines 64-72).

Applicants' argument that the valve of McKim lacks the required flexibility of applicant's invention is disagreed with because McKim (figs.1 and 3) illustrates flexibility of the valve flap (14). Further, the manner of bending illustrated in figs.1 and 3 of McKim is consistent with appellants definition of a "...the flap can form or bend in the form of a self-supporting arc when secured at one end as a cantilever and view from a side elevation...". Finally, no particular degree of flexibility is quantitatively and/or structurally defined in any manner which is unobvious over the prior art combination of Simpson et al. as modified by McKim.

Applicants' assertion that the examiner has not provided any teaching, suggestion or motivation to combine the prior art to Simpson et al. and McKim is not accurate. As set forth above in the body of the rejection, the reason for combination of Simpson et al. with McKim is because it would have provided for quick effective seating without float or bounce after each opening as taught by McKim (col.1, lines 64-72).

Applicants' assertion that Simpson et al. and McKim each present very good evidence of a lack of motivation to combine their respective teachings because no one of ordinary skill in the respirator art has made use of the teachings of McKim in making an exhalation valve is not accurate because examples of the use of the manner of mouting valves as taught by McKim do exist in the respirator art. The mounting of flapper valves in the respirator art by clamping a stationary portion of the flap in a different plane than the sealing surface (i.e. seat) resulting in a curved configuration which physically biases a free end of the valve to a closed position is well known (see fig.3 of Simpson et al.). Another example is seen in the prior art to Matheson (cited but not applied) U.S. Patent 2,999,498, fig.8 and col.1, lines 38-46.

Applicants' arguments that the time between issuance of patents to Simpson et al. and McKim is evidence for a lack of combination is disagreed with because the time between the two does not preclude one of ordinary skill from appreciating the teachings and benefits disclosed by each of the documents separately and in combination.

Conclusion

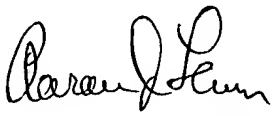
6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. LEWIS whose telephone number is (703) 308-0716. The examiner can normally be reached on 9:30AM-6:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, HENRY A. BENNETT can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



AARON J. LEWIS
Primary Examiner
Art Unit 3743

Aaron J. Lewis
November 03, 2003